

SEP - 7 2000

Section 6
510(k) Summary

Nobel Biocare USA Letterhead

1K000643

510(k) Summary

A. Device Name and Classification:

Common Name:	Dental Implant
Trade Name:	Nobel Biocare's InPlant™ Orthodontic Anchor System
Classification Name:	Endosseous Dental Implant
Classification Number:	DZE
Classification Citation:	21 CFR 872.3640

B. Submitter Information:

Submitter's Name and Address:

Nobel Biocare USA, Inc.
22825 Eastpark Drive
Yorba Linda, CA 92887 USA

Contact's Name: Jeff Hausheer, Ph.D.
Regulatory Affairs Specialist

Contact's Telephone No.: 714-282-4800, extension 7832

Date Prepared: February 18, 2000

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C. Manufacturer Information:

Manufacture's Name and Address(es):

- | | | |
|---|---|---------------------|
| 1) Manufacturer Name:
Address: | Nobel Biocare AB
Dimbovagen 2
Karlskoga S-691-51, SWEDEN | Reg'n No.: 9611993 |
| 2) Manufacturer Name:
Address: | Nobel Biocare AB
P.O. Box 5211
SE-402 24 Göteborg, SWEDEN | Reg'n. No.: 9611993 |
| 3) Manufacturer Name:
Address: | Nobel Biocare USA, Inc.
22895 Eastpark Drive
Yorba Linda, CA 92887, USA | Reg'n No.: 2027763 |
| 4) Manufacturer Name:
Address: | Nobel Biocare USA, Inc.
22725 Savi Ranch Parkway
Yorba Linda, CA 92887, USA | Reg'n No.: 2027971 |
| 5) Sterilizer ¹ :
Address | Nobel Biocare AB
Dimbovagen 2
Karlskoga S-691-51 | Reg'n No.: 9611993 |
| 6) Sterilizer ² :
Address | Steri-Genics Intl., Inc.
344 Bonnie Circle
Corona, CA 91720 2897, USA | Reg'n No.: 2029275 |

¹ Nobel Biocare AB (Karlskoga) will sterilize product manufactured in Sweden.

² Steri-Genics Int'l. will sterilize product manufactured at Nobel Biocare USA, Yorba Linda, CA

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D. Device Description:

The InPlant™ Orthodontic Anchor is an osseointegrated implant, which when subjected to normal orthodontic forces will remain in its original position throughout the duration of the patient's orthodontic treatment. The InPlant™ Anchor, made of titanium, is a small, one-piece, threaded root-form implant. The Anchor has a 50 micron thick hydroxyapatite-coating on the threaded portion of the implant body to facilitate osseointegration into the bone; above the threaded portion is a cylindrical, transepithelial sleeve (abutment portion), and above that is a head portion, which has design features that provide for the attachment of orthodontic appliances such as wires, rubber bands and springs.

The InPlant™ Cap, made of stainless steel, is designed to allow orthodontic anchoring elements such as tubes or brackets to be attached to the Cap by welding or soldering. The InPlant™ Cap is then, in turn, cemented onto the head of an InPlant™ Anchor.

E. Intended Use:

InPlant™ Anchor

The InPlant™ Orthodontic Anchor is a small, threaded, titanium dental implant that, after achieving osseointegration, is intended to serve as a fixed anchorage point to which orthodontic appliances (such as rubber bands, wires, and springs) can be attached.

The InPlant™ Orthodontic Anchor can be used intra-orally wherever there is at least 3.0-mm bone thickness available for placement of the Anchor.

Several InPlant™ Anchors can be connected together to meet anchorage needs in more complex orthodontic situations.

When subjected to normal orthodontic forces (≤ 4.9 Newtons), an osseointegrated InPlant™ Anchor will remain in the exact position in which it was placed throughout the course of the patient's orthodontic treatment.

InPlant™ Cap

The InPlant™ Orthodontic Cap is a stainless steel base to which orthodontic brackets, tubes or other orthodontic components can be welded or soldered. The cap is then cemented onto the InPlant Anchor's head for anchorage.

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F. Basis For Substantial Equivalence & Comparison to the Predicate Device(s):

The predicate devices with which substantial equivalence is claimed are identified in Table 6.1. The intended uses of the predicate devices are compared with those of the InPlant™ Anchor and the InPlant™ Cap in Table 6.2. In Table 6.3, the technological characteristics of the InPlant™ Anchor are compared with those of the predicate devices, and in Table 6.4, the technological characteristics of the InPlant™ Cap are compared with those of the predicate device "Caps".

Table 6.1
Identification of the Predicate Devices and the Submitted Device

Product	510(k) # (and Manufacturer)	Status
InPlant™ Orthodontic Anchor System	K # pending Nobel Biocare USA	Submitted Device
"Ortho Implant and Accessories"	K982509 9/30/98 Straumann USA	Predicate #1
Orthodontic Abutment "Orthobutment" I	K980083 8/17/98 3I Implant Innovations	Predicate #2
OnPlant™ Orthodontic Anchor System	K980460 5/5/98 Nobel Biocare USA	Predicate #3

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Table 6.2.
Intended Use: Comparison of the Predicate Devices and the Submitted Device

Predicate	Intended Use [from 510(k) Summary]	Indications For Use [from 510(k) Summary]
Predicate No. 1: Straumann's "Ortho" Implant and Accessories	The Ortho implant of the Straumann Orthosystem is an endosseous implant intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed.	"The Ortho implant of the Straumann Orthosystem is an endosseous implant intended for placement in the median palatal region or in retromolar positions." "Its purpose is to provide a fixed anchorage point for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth." "It is used temporarily and is intended to be removed after orthodontic treatment has been completed."
Predicate No. 2: 3I Implant Innovations "Orthodontic Abutment" Orthodontic	[510(k) Summary does not contain a separate "Intended Use" statement.]	"The 3I orthodontic abutment with 3I's endosseous dental implant system is (are) indicated for use in orthodontic procedures, in which prior edentulism permits implantation of a root form implant into jaw arches (alveolar bone), as an anchor for fixation and abutment (support) of an orthodontic appliances
Predicate No. 3: On-Plant™ Orthodontic Anchor System	The Nobel Biocare OnPlant Orthodontic System is an implant intended to be surgically placed subperiosteally in the palatal region of the mouth for use as an anchor for orthodontic procedures in patients who have completed skeletal growth and maturity.	The Nobel Biocare OnPlant Orthodontic System is an implant intended to be surgically placed subperiosteally in the palatal region of the mouth for use as an anchor for orthodontic procedures in patients who have completed skeletal growth and maturity.
Submitted Device Nobel Biocare's InPlant Orthodontic Anchor System	<u>InPlant™ Anchor:</u> The InPlant™ Anchor, a small endosseous implant, is used as an orthodontic anchor to which orthodontic appliances such as rubber bands, wires and springs can be attached. <u>InPlant™ Cap:</u> The cap is a stainless steel base to which orthodontic brackets, tubes, etc. can be welded or soldered. The Cap is then cemented onto the InPlant™ Anchor head for anchorage.	InPlant™ Anchor is an osseointegrated anchor, which when subjected to normal orthodontic forces (<4.9 N) will remain in its exact position throughout the orthodontic treatment phase. InPlant™ Anchors can be used intra-orally wherever there is 3-mm bone thickness, or more, available for placement. Several InPlant™ Anchors can be connected together for more complex anchoring situations.

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Table 6.3: IMPLANT ANCHOR: Technology: Comparison of the Predicate Devices and the Submitted Device*

Attribute/ Characteristic	Predicate No. 1 "Ortho Implant & Accessories"	Predicate No. 2 Orthodontic Abutment "Orthobutment"	Predicate No. 3 OnPlant™ Orthodontic Anchor	Submitted Device: InPlant™ Orthodontic Anchor
Design	Threaded, tapered, root-form dental implant	Cylindrical abutment-like "cap"; a modified implant abutment	One-piece endosseous, surface integrated disk	SAME (predicate #1)
Principles of Functioning	Integrated root-form implant provides fixed orthodontic anchor	Integrated root-form implant provides fixed orthodontic anchor	Surface integrated implant provides fixed orthodontic anchor	SAME (predicates #1, #2, & #3)
Material	Titanium (CP Grade 4)	Titanium (CP Grade 1)	Titanium (CP Grade 1)	SAME (predicates #2 & #3)
Coating/Surface Properties	Sandblasted & etched	Sandblasted & etched	Hydroxyapatite (50 microns thick, threaded portion of body only)	SAME (predicate #3)
Overall Length	4.0-mm & 6.0-mm	2.9-mm	2.9-mm ("height")	7.0-mm to 8.5-mm
Collar/Neck Portion Length	2.5-mm and 4.5-mm	Not Applicable	Not Applicable	1.5-mm to 3.0-mm**
Threaded Portion of Length Diameter	3.3-mm	7.7-mm and 9.0-mm	7.7-mm and 9.0-mm	3.5-mm
Packaging	Unknown	Not Applicable	Not Applicable	3.0-mm to 6.0-mm***
Sterility (How Supplied)	Sterile	Chevron Bag in Plastic Vial/Box	Chevron Bag in Plastic Vial/Box	2.5-mm to 3.25-mm
				SAME (predicates #2 & #3)
				SAME (predicates #1, #2, & #3)

* = The 510(k) under which each product was made available for commercialization is identified in Table 6.1.
 ** = Anchor is placed transeptal. The anchor to be used is selected based on the depth of the patient's gingiva.
 *** = Anchor is placed anywhere intra-orally provided there is at least 3.0-mm of bone available at the anchor site.

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Table 6.4
IMPLANT CAP

Technology: Comparison of the Predicate Devices and the Submitted Device

Attribute / Characteristic	Predicate No. 1 "Ortho Bonding Base"	Predicate No. 2 Orthodontic Abutment "Orthobutment"	Predicate No. 3 OnPlant™ Orthodontic Anchor	Submitted Device: InPlant™ Orthodontic Anchor
510(k) No.	K982509	K980083	K980460	To Be Assigned
Design/Material	One-Piece	One Piece	One Piece	Same (predicates #1, #2, & #3)
Function/Purpose	Point of attachment for orthodontic appliances	Point of attachment for orthodontic appliances	Point of attachment for orthodontic appliances	Same (predicates #1, #2, & #3)
Mode of Attachment	Screw retained	Screw Retained	Screw retained	Cemented
Material	Titanium	Stainless Steel	Stainless Steel	Stainless Steel
Overall Length (millimeters)	4.0-mm	3.5mm	3.5mm	2.8-mm
Diameter (millimeters)	6.0-mm	5.0mm	5.0mm	3.5-mm
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP - 7 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jeff Hausheer, Ph.D.
Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22895 Eastpark Drive
Yorba Linda, California 92887

Re: K000643

Trade Name: InPlant™ Orthodontic Anchor System
Regulatory Class: III
Product Code: DZE
Dated: February 18, 2000
Received: February 25, 2000

Dear Dr. Hausheer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

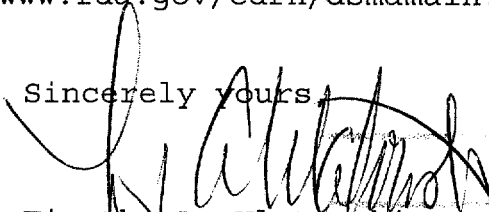
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 9
Indications for Use

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510(k) Number (if known): K00XXXX

Device Name:

Nobel Biocare's InPlant™ Orthodontic Anchor System

⇒ InPlant™ Anchor

⇒ InPlant™ Cap

Indications for Use:

⇒ InPlant™ Anchor

The InPlant™ Orthodontic Anchor is a small, threaded, titanium dental implant that, after intra-oral placement and osseointegration, is intended to serve as a fixed anchorage point for the attachment of orthodontic appliances (such as rubber bands, wires, and springs).

The InPlant™ Orthodontic Anchor can be used intra-orally wherever there is at least 3.0-mm bone thickness available for placement of the Anchor.

Several InPlant™ Anchors can be connected together to meet anchorage needs in more complex orthodontic situations.

⇒ InPlant™ Cap

The InPlant™ Orthodontic Cap is a stainless steel base to which orthodontic brackets, tubes or other orthodontic components can be welded or soldered. The cap is then cemented onto the InPlant Anchor's head for anchorage.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Susan R. [Signature]
(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number 9006643

Prescription Use ☒

OR Over-The-Counter Use ☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)